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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,111	04/19/2004	Catherine Tachdjian	13099.0023U2	1476

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EXAMINER	
COVINGTON, RAYMOND K	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/827,111	TACHDJIAN ET AL.	
	Examiner	Art Unit	
	Raymond Covington	1625	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/10/05 11/3/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/10/05 11/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Pfahl et al US 6,515,003.

Pfahl et al teach heterocyclic substituted thiazoline compounds and their use as recited in applicants' claims corresponding to the formula in claim 1. See, for example, columns 1-3 and claims 1 and 15.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfahl et al US 6,515,003

Determination of the scope and content of the prior art (MPEP 2141.01)

Pfahl et al teach heterocyclic substituted thiazoline compounds and their use as recited in applicants' claims corresponding to the formula in claim 1. See, for example, columns 1-3 and claims 1 and 15.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Pfahl et al differs in the heterocyclic linking group employed between the bicyclic and thiazoline moiety.

Finding of prima facie obviousness--rational and motivation (MPEP 2142-2413)

However, in view of the art as a whole and the close structural relationship between the compounds and linking groups as a whole it would have been obvious to one of ordinary skill in the art to modify Pfahl et al to employ other analogous heterocyclic linking groups as the use of somewhat different but other analogous groups would not have been unexpected and therefore unpatentable.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-26 and 40-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention: The nature of the invention is compounds for the treatment of uncontrolled cellular proliferation.

The state of the prior art and predictability: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art

from accepting any therapeutic regimen on its face. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable given the unpredictability of treating cancer.

Guidance and working examples: Compounds according to the invention have been made. The assay test is noted. While screening test in an enzyme assay provides data in picking and choosing lead compounds for further testing, screening test per se does not provide sufficient operational guidance in an 'individual' in patho-physiological environment.

It is not clear that the assays correlate to any form of cancer treatment. There is no evidence of functional treatment, i.e. no correlation to treatment in humans. Applicants have not shown the claimed compounds effective to treat all cancers. Applicants' assertions either that the compounds would be effective *or* that the compounds are effective are not enough. It has yet to be established that the claimed compounds have a viable utility which is why they are included in the rejection.

The instant method of treatment/inhibition of cancer as recited in the claims encompasses such unidentified forms of cancer/tumor growth, a description of which is not found in the specification.

No class of compounds or single compound has been found effective in treating, such a myriad of unrelated cancers, diseases or disorders. Cancer treatment has been known to be compound and disease specific, that is a particular class of compounds or compound is useful in treating a particular cancer or type of cancers.

No single compound or class of compounds is known to treat all the sub-categories of a particular type of disease or disorder. By way of example, applicants name diseases or disorders associated with ---inflammatory reactions, abnormal angiogenesis affecting body tissue, cancer, and degenerative changes within the walls of blood vessels---. Applicants' are attempting to claim every known associated disease or disorder with the above conditions as well as future diseases and disorders and such is wholly inoperable.

This is particularly true with respect to claims 18 and 45 in that it is not clear whether the desired effect is gained by modulating lipid metabolism up to modulating lipid metabolism down.

The instant method of treatment/inhibition of cancer with additional anticancer agents as recited in the claims encompasses such unidentified anticancer agents, a description of which is not found in the specification.

The 'how to use' requirements of 35 USC 112 are not met by disclosing only a pharmaceutical activity of the clamed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. Where a therapeutic effect on humans is disclosed, such as treating cancer, more than mere assertions or screening data is needed unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. The instantly claimed compounds are not structurally similar to known compounds having the same activity and their pharmacological properties can not be predicted from their chemical structure, thus a disclosure that they possess a particular activity is not enough.

Thus, the specification fails to provide sufficient support of the use of the compounds of the claim for the treatment of all cancers. As a result necessitating one of ordinary skill to perform an exhaustive search for which compounds of the claims can treat all cancers in order to practice the claimed invention.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond Covington
Examiner
Art Unit 1625

RKC

9/21/05